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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,559	05/14/2002	Masayuki Yanagi	2026-4302US	8862

7590 09/22/2004

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,559	YANAGI ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 37-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 8, filed 06/28/04. Claims 1 and 12-36 have been canceled. Claims 2-5, 37 have been amended. New claims 38 and 39 have been added. Claims 2-5 and 37-39 are pending.

Pease note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 and 4-11 are still rejected under 35 U.S.C. 102(b) as anticipated by Okamoto et al. (J. Gen. Virol. 1991, Vol. 72, pp. 2697-2704) in light of disclosure of Doorn et al. (J. Gen. Virol. 1995, Vol. 76, pp. 1871-1876, see Fig. 1 on page 1873) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Okamoto et al. (J. Gen. Virol. 1991, Vol. 72, pp. 2697-2704) and further in view of Yoo et al. (J. Virol. 1995, Vol. 69, No. 1, pp. 32-38).

4. In response to the previous Office Action, Applicants amended claims to an isolated nucleic acid molecule encodings human HCV of genotype 2a, which encodes the amino acid sequence that differs from amino acid sequence of SEQ ID NO: 2 by < 2% at the amino acid

level or a DNA construct or RNA transcript as well as cell transfected with the DNA or RNA comprising same. Applicants traverse the rejection and submitted that the invention now relates to a nucleic acid sequence, which encodes infectious hepatitis C virus of strain HC-$J6_{CH}$, genotype 2a that is different from the experimentally infected chimpnnzee HCV-J6 identified by Okamoto et al., (1991) by 4.1% and 2.2% at the nucleotide and deduced amino acid levels, respectively (Fig. 2, Table 2). Therefore, the nucleic acid disclosed by Okamoto et al. should not anticipate the rejected claims.

5. Applicants' argument has been considered, however, it is not found persuasive. Because after comparing the nucleic acid sequence encoding the amino acids of SEQ ID NO: 2 with the cDAN sequence of HCV-J6 genome type 2a (SEQ ID NO: 2), it is found that the claimed nucleic acid molecule has 98.78% homology to the SEQ ID NO: 2 that encodes the cDNA of HCV-J6 disclosed by Okamoto et al. cited by the prior Office Action.

New Ground Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 4-7 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kokamoto et al. (EP 532 167A2).

8. Okamoto et al. disclose several isolated nucleic acid molecules encoding HCV genotype 2a variants, which include the whole nucleotides of HCV-J6 genomic RNA (SEQ ID NO: 1), and a cDNA (SEQ ID NO: 2) to the HCV-J6 genomic RNA, wherein the cDNA of SEQ ID NO: 2 has 98.78% homology to the nucleic acid sequence encoding the claimed amino acid sequence of SEQ ID NO: 2 in current application (See lines 34-37 on page and claims 1-2). Okamoto et al. also teach that the isolated HCV-J6 RNA sample is resuspended in a composition comprising Tris chloride buffer (50 mM, pH 8.0) with 200 mM NaCl etc, which is a pharmaceutical

accepted diluent and exciepinet (See line 40-44 on page 5). Therefore, the claimed invention is anticipated by the cited reference.

9. Claims 2, 4-7 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kokamoto et al. (US Patent No. 5/428,145A).

10. Okamoto et al. disclose several isolated nucleic acid molecules encoding HCV genotype 2a variants, which include the whole nucleotides of HCV-J6 genomic RNA (SEQ ID NO: 1), and a cDNA (SEQ ID NO: 2) to the HCV-J6 genomic RNA, wherein the cDNA of SEQ ID NO: 2 has 98.78% homology to the nucleic acid sequence encoding the claimed amino acid sequence of SEQ ID NO: 2 in claim 2 of current application (See lines 40-51 on col. 12 and claims 1-6). Okamoto et al. also teach that the isolated HCV-J6 RNA sample is resuspended in a composition comprising Tris chloride buffer (50 mM, pH 8.0) with 200 mM NaCl etc, which is a pharmaceutical accepted diluent and exciepinet (See lines 24-34 on col. 6). Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokamoto et al. (US Patent No. 5/428,145A) and Yoo et al. (J. Virol. 1995, Vol. 69, No. 1, pp. 32-38).

13. Claimed invention is drawn to the host cell transfected with RNA or DNA of an isolated HCV-J6 virus, wherein the DNA sequence encodes the amino acids that has less than 2% homology to the SEQ ID NO: 2.

14. Okamoto et al. disclose several isolated nucleic acid molecules encoding HCV genotype 2a variants, which include the whole nucleotides of HCV-J6 genomic RNA (SEQ ID NO: 1), and a cDNA (SEQ ID NO: 2) to the HCV-J6 genomic RNA, wherein the cDNA of SEQ ID NO: 2

has 98.78% homology to the nucleic acid sequence encoding the claimed amino acid sequence of SEQ ID NO: 2 in claim 2 of current application (See lines 40-51 on col. 12 and claims 1-6). While Okamoto et al. do not explicitly disclose a host cell transfected with such nucleic acid molecule, they teach that the polynucleotide with those identified sequences can be used to express polypeptide in host cells such as Escherichia coli by the well-know genetic engineering technique (See lines 46-48 on page 12).

15. Yoo et al. explicitly teach a method for using the Huh7 cells to establish the long-term culture persistently express HCV by transfecting the cells with the HCV RNA transcript and establish the cell line harboring the HCV RNA or DNA molecule (See entire document, especially the first col. of page 33).

16. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated by the disclosed prior art to express the HCV virus in view of the technique taught by Yoo et al. and establish a host cell line harboring the isolated HCV nucleic acid molecule. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

17. Claims 3 and 38-39 are free of rejection. However, they are not in the condition for allowance because they depend on the rejected claims. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Bao Qun Li
Art Unit 1648
09/05/2004